UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

November 10, 2022
Date of Report (date of earliest event reported)

LISATA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-33650**	**22-2343568**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

110 Allen Road, Second Floor, Basking Ridge, NJ 07920
(Address of Principal Executive Offices)(ZipCode)
(908) 842-0100
Registrant's telephone number, including area code

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	LSTA	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

☐ Emerging growth company

o If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

The information in Item 7.01 is incorporated by reference.

Item 7.01 Regulation FD Disclosure.

On November 10, 2022, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the third quarter ended September 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

A copy of a slide presentation that the Company will use at investor and industry conferences and presentations is attached to this Current Report as Exhibit 99.2 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 10, 2022
99.2	Lisata Therapeutics, Inc. Corporate Presentation, November 10, 2022

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LISATA THERAPEUTICS, INC.

By: /s/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: Chief Executive Officer

Dated: November 10, 2022

Exhibit 99.1

Lisata Therapeutics Reports Third Quarter 2022 Financial Results and Provides Business Update

Conference call scheduled for today at 4:30 p.m. Eastern time

- *Post-merger profile describes rich clinical development pipeline backed by solid financial situation*
- *Qilu Pharmaceutical Phase 1b/2 study of LSTA1 in China ongoing; Preliminary data expected in the second half of 2023*
- *Phase 2b study of LSTA1 in Australia/New Zealand (ASCEND) and LSTA1 Phase 1b/2 study in the U.S. (CENDIFOX) remain on track to complete enrollment in late 2023/early 2024; Data expected in 2024*
- *Company expects to initiate clinical trials of LSTA1 in the first half of 2023 for the treatment of various solid tumors and additional combination therapies, with multiple key milestones anticipated in the next 12 to 24 months*

BASKING RIDGE, NJ (November 10, 2022) – Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata" or the "Company"), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, today announced its financial results for the three and nine months ended September 30, 2022 and provided a business update.

"We are excited to report our first quarter as Lisata Therapeutics following the merger of Caladrius Biosciences and Cend Therapeutics," stated David J. Mazzo, Ph.D., Chief Executive Officer of Lisata. "The team has made tremendous progress over the past few months and now, as Lisata, we are building an enduring pharmaceutical company for the treatment of diseases with significant unmet medical needs. As such, our primary focus is the advancement of our clinical development pipeline of candidates targeting oncology and ischemic disease indications. LSTA1, our lead investigational product candidate from the CendR Platform™, is the subject of multiple planned and ongoing clinical trials being conducted globally in a variety of solid tumor types and in combination with several chemotherapy and immunotherapy anti-cancer regimens. We believe that LSTA1 has the potential to become an integral part of a revised standard-of-care therapy for many difficult to treat cancers. Recent guidance from the U.S. Food and Drug Administration has given us further direction on what would be required for registration. We have discussed this guidance with our development partners and we are planning adjustments to protocols, including the modification and expansion of ongoing studies.

Dr. Mazzo continued, "Overall, we're invigorated by the promise of our platform technologies and pipeline of product and partnering opportunities and look forward to providing updates on our progress in the coming months."

Development Portfolio Update

LSTA1 as a treatment for solid tumor cancers in combination with other anti-cancer agents

LSTA1, formerly known as CEND-1, is an investigational drug that actuates the CendR active transport mechanism while also having the potential to modify the tumor microenvironment ("TME") and make is less immunosuppressive. It is targeted to tumor vasculature by its affinity for alpha-v, beta-3 and beta-5 integrins that are selectively expressed in tumor vasculature, but not healthy tissue. LSTA1 is a specific cyclic internalizing RGD ("iRGD") peptide that, once bound to these integrins, is cleaved by proteases expressed in tumors to release a peptide fragment, called a CendR fragment, which binds to a second receptor, called neuropilin-1, to activate a novel uptake pathway that allows anticancer drugs to more selectively penetrate solid tumors. The ability of LSTA1 and iRGD peptides to modify the TME to enhance delivery and efficacy of co-administered drugs has been demonstrated in models of a range of solid tumors with the results from Lisata, collaborators and research groups around the world having been the subject of over 200 scientific publications. Lisata and its collaborators have also amassed significant non-clinical data demonstrating enhanced delivery of a range of emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. Clinically, LSTA1 has demonstrated favorable safety, tolerability, and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. Currently, LSTA1 is the subject of Phase 1b/2a and 2b clinical studies

being conducted globally in various solid tumors, including metastatic pancreatic ductal adenocarcinoma, in combination with a variety of anti-cancer regimens. The combination of LSTA1 with corresponding standards-of-care in other solid tumor indications is planned for clinical study in the first half of 2023.

HONEDRA® (LSTA12, aka CLBS12) for the treatment of critical limb ischemia ("CLI")

HONEDRA® is the Company's SAKIGAKE-designated product candidate for the treatment of CLI and Buerger's disease in Japan, which is now in the pre-consultation phase of the registration process with the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan. Data from the follow-up of all patients completed in the registration-eligible clinical trial in Japan have been compiled and are being reviewed by the PMDA, after which the PMDA is expected to provide important perspective to be considered in preparation for the formal consultation meetings which precede the Japanese new drug application. If successful in the pre-consultation process, Lisata expects formal clinical consultation to occur by mid-year 2023. Concomitantly, the Company is focusing its efforts to secure a Japanese partner to complete the remaining steps to produce registration in Japan.

XOWNA® (LSTA16, aka CLBS16) for the treatment of coronary microvascular dysfunction ("CMD")

XOWNA® is an experimental regenerative therapy for the treatment of CMD. It was the subject of a positive Phase 2a study (the "ESCaPE-CMD trial") reported in 2020 and is currently being evaluated in a U.S. Phase 2b study (the "FREEDOM Trial"). The FREEDOM Trial was originally designed as a 105-patient double-blind, randomized, placebo-controlled trial to further evaluate the efficacy and safety of intracoronary delivery of autologous CD34+ cells (XOWNA®) in subjects with CMD and without obstructive coronary artery disease and was expected to complete enrollment in approximately 12 months. As previously disclosed, enrollment in the FREEDOM Trial initially proceeded as planned with the first patient treated in January 2021; however, the impact of the COVID-19 pandemic in the U.S., coupled with supply chain issues associated with the catheters used for diagnosis of CMD and/or administration of XOWNA®, as well as with a contrast agent typically used in many catheter laboratories, have made and continue to make enrollment much slower than originally predicted and challenging to accelerate. As a result, the Company announced that enrollment in the FREEDOM Trial had been suspended and that it intended to conduct an interim analysis of the data from not less than the first 20 patients enrolled using the 6-month follow-up data to evaluate the efficacy and safety of XOWNA® in subjects with CMD. Following the analysis of results of the FREEDOM Trial subjects completing 6-month follow-up along with Key Opinion Leaders' input, the Company's board of directors determined that execution of a redesigned FREEDOM-like trial would be the appropriate next step, but the cost of such a trial would be prohibitively expensive to undergo alone and without a strategic partner. Accordingly, the Company's board of directors concluded that XOWNA® development will only be continued if a strategic partner that can contribute the necessary capital for a redesigned trial is identified and secured.

LSTA201 (aka CLBS201) for the treatment of diabetic kidney disease ("DKD")

Progressive kidney failure is associated with attrition of the microcirculation of the kidney. Preclinical studies in kidney disease and injury models have demonstrated that protection or replenishment of the microcirculation results in improved kidney function. Based on these observations, the Company initiated a Phase 1b, open-label, proof-of-concept trial evaluating LSTA201, a CD34+ regenerative cell therapy investigational product for intra-renal artery administration in patients with DKD. Patients selected for the study are in the pre-dialysis stage of kidney disease and exhibit rapidly progressing stage 3b disease. The protocol provides for a cohort of six patients overseen by an independent Data Safety Monitoring Board with the objective of determining the tolerance of intra-renal cell therapy injection in DKD patients as well as the ability of LSTA201 to regenerate kidney function. A key read-out of data will occur at the 6-month follow-up visit for all patients. The Company treated the first patient in April 2022 and completed treatment for all six subjects during the third quarter of 2022. Top-line data is anticipated from all subjects by the first quarter of 2023.

Third Quarter 2022 Financial Highlights

Research and development expenses were approximately $3.4 million for the three months ended September 30, 2022, compared to $4.1 million for the three months ended September 30, 2021, representing a decrease of $0.7 million or 18.1%. This was primarily due to a decrease in expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial) as a result of the suspension in enrollment which commenced in the second quarter of 2022 and study close out activities in the third quarter of 2022, a decrease in expenses associated with HONEDRA® in Japan related to study close out costs partially offset by the addition of Chemistry, Manufacturing, and Controls ("CMC") activities for LSTA1, and enrollment activities for Australasian Gastrointestinal Trials Group ("AGITG") ASCEND study. Research and development in both periods related to:

- expenses associated with our XOWNA® Phase 2b study (the FREEDOM Trial);

- expenses associated with our registration-eligible study for HONEDRA® in CLI in Japan as well as corresponding regulatory discussions and support expenses;
- expenses associated with the preparation of our filing of an Investigational New Drug Application, as well as study execution expenses for the clinical study of LSTA201 for treatment of DKD, a Phase 1b, open-label, proof-of-concept trial which includes six subjects in total;
- expenses associated with the addition of CMC activities for LSTA1, enrollment activities for the LSTA1 Phase 2b ASCEND study and preparatory activities associated with the design of a planned LSTA1 proof-of-concept basket trial in various solid tumors and in combination with the corresponding standards of care.

General and administrative expenses, which focus on general corporate related activities, were $3.9 million for the three months ended September 30, 2022, compared to $2.8 million for the three months ended September 30, 2021, representing an increase of 39%. This increase was primarily due to an increase in equity expense as a result of performance stock unit vesting, a one-time merger option assumption expense and departing board member restricted stock unit vesting in addition to an increase in expenses associated with our annual stockholder meeting and the merger.

Net losses were $37.4 million for the three months ended September 30, 2022, compared to $6.9 million for the three months ended September 30, 2021.

Balance Sheet Highlights

As of September 30, 2022, the Company had cash, cash equivalents and marketable securities of approximately $75.5 million.

Conference Call Information

Lisata will hold a live conference call today, November 10, 2022, at 4:30 p.m. Eastern time to discuss financial results, provide a business update and answer questions.

The Company is utilizing a new conference call service. Those wishing to participate must register for the conference call by way of the following link: https://register.vevent.com/register/BIb133855aa28547eda1ae5e1e1da0559c. Registered participants will receive an email containing conference call details for dial-in options. To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time.

A live webcast of the call will also be accessible under the Investors & News section of Lisata's website (available at this link: https://ir.lisata.com) and will be available for replay beginning two hours after the conclusion of the call for 12 months.

About Lisata Therapeutics

Lisata Therapeutics is a clinical-stage pharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies for the treatment of advanced solid tumors and other major diseases. Lisata's lead investigational product candidate, LSTA1 (formerly known as CEND-1), is designed to modify the tumor microenvironment by activating a novel uptake pathway that allows anti-cancer drugs to penetrate solid tumors more effectively. LSTA1 actuates an active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, while normal tissues are not affected. LSTA1 has demonstrated favorable safety, tolerability, and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Lisata and its collaborators have also amassed significant non-clinical data demonstrating enhanced delivery of a range of emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. In addition, Lisata also has clinical development programs based on its autologous CD34+ cell therapy technology platform. For more information on the Company, please visit www.lisata.com.

Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Lisata or its management, may identify forward-looking statements.

Examples of forward-looking statements include, but are not limited to, statements relating to the long-term success of Lisata's recently completed merger (the "Merger") with Cend Therapeutics, Inc. ("Cend"), including the ongoing integration of Cend's operations; Lisata's continued listing on the Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of Lisata; the approach Lisata is taking to discover and develop novel therapeutics; the adequacy of Lisata's capital to support its future operations and its ability to successfully initiate and complete clinical trials; and the difficulty in predicting the time and cost of development of Lisata's product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the ongoing COVID-19 pandemic on Lisata's business, the safety and efficacy of Lisata's product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in Lisata's clinical programs, Lisata's ability to finance its operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of Lisata's scientific studies, Lisata's ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in Lisata's markets, the ability of Lisata to protect its intellectual property rights; unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the completion of the Merger; potential underperformance of Lisata's business following the Merger as compared to management's initial expectations; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Lisata's Annual Report on Form 10-K filed with the SEC on March 22, 2022 and Exhibit 99.2 to Lisata's Amendment No. 1 to Current Report on Form 8-K filed on October 4, 2022, and in other documents filed by Lisata with the Securities and Exchange Commission. Except as required by applicable law, Lisata undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Contact:

Investors and Media:
Lisata Therapeutics, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@lisata.com

- Tables to Follow -

Lisata Therapeutics, Inc.
Selected Financial Data
(in thousands, except per share data)

(in thousands, except per share data)	Three Months Ended September 30, 2022 (unaudited)	Three Months Ended September 30, 2021 (unaudited)	Nine Months Ended September 30, 2022 (unaudited)	Nine Months Ended September 30, 2021 (unaudited)
Statement of Operations Data:				
Research and development	$ 3,380	$ 4,125	$ 9,898	$ 13,530
In-process research and development	30,393	—	30,393	—
General and administrative	3,947	2,843	10,770	8,671
Total operating expenses	**37,720**	**6,968**	**51,061**	**22,201**
Operating loss	**(37,720)**	**(6,968)**	**(51,061)**	**(22,201)**
Investment income, net	337	41	496	111
Other expense, net	—	—	(149)	(90)
Net loss before benefit from income taxes and noncontrolling interests	**(37,383)**	**(6,927)**	**(50,714)**	**(22,180)**
Benefit from income taxes	—	—	(2,479)	(1,508)
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (37,383)**	**$ (6,927)**	**$ (48,235)**	**$ (20,672)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (7.88)**	**$ (1.74)**	**$ (11.28)**	**$ (5.76)**
Weighted average common shares outstanding	**4,747**	**3,974**	**4,276**	**3,587**

	September 30, 2022 (unaudited)	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$75,530	$94,970
Total assets	78,529	97,008
Total liabilities	6,758	5,008
Total equity	71,771	92,000

# # #

EXHIBIT 99.2

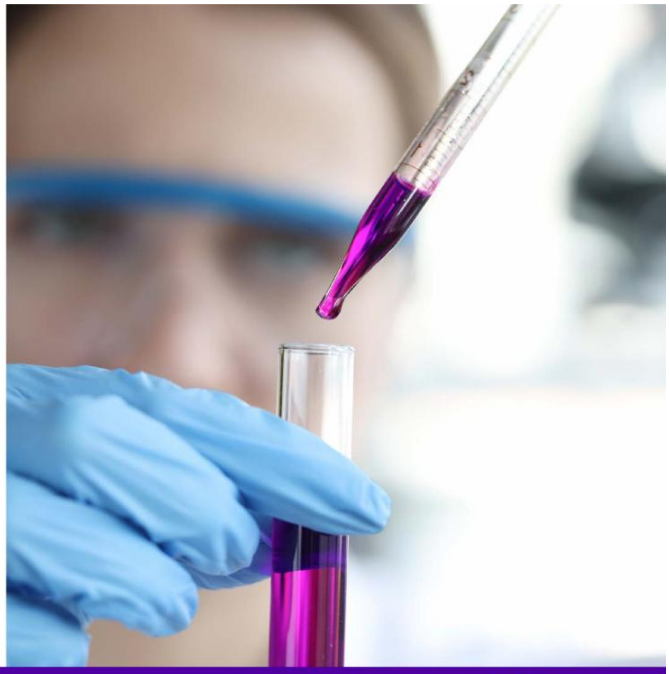
LISATA THERAPEUTICS

Targeted Therapy **Delivered**

David J. Mazzo, Ph.D.
Chief Executive Officer

Corporate Presentation | November 10, 2022
Nasdaq: LSTA

www.lisata.com



Forward-looking Statements

This presentation contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict", target and similar expressions and their variants, as they relate to Lisata or its management, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the long-term success of Lisata's recently completed merger (the "Merger") with Cend Therapeutics, Inc. ("Cend"), including the ongoing integration of Cend's operations; Lisata's continued listing on the Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of Lisata; the approach Lisata is taking to discover, develop and commercialize novel therapeutics; the adequacy of Lisata's capital to support its future operations and its ability to successfully initiate and complete clinical trials; and the difficulty in predicting the time and cost of development of Lisata's product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the impact of the ongoing COVID-19 pandemic on Lisata's business, the safety and efficacy of Lisata's product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in Lisata's clinical programs, Lisata's ability to finance its operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of Lisata's scientific studies, Lisata's ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in Lisata's markets, the ability of Lisata to protect its intellectual property rights; unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the completion of the Merger; potential underperformance of Lisata's business following the Merger as compared to management's initial expectations; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Lisata's Annual Report on Form 10-K filed with the SEC on March 22, 2022, and in the proxy statement/prospectus filed by Lisata with the Securities and Exchange Commission relating to the Merger. Except as required by applicable law, Lisata undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Investment highlights

| NOVEL TECHNOLOGY TO IMPROVE EFFICACY OF ANTI-CANCER DRUGS FOR SOLID TUMORS |

| EXISTING CAPITAL EXPECTED TO FUND ANTICIPATED MILESTONES | EXISTING STRATEGIC PARTNERSHIPS |

- Nasdaq-listed with a focused mid-late-stage clinical development pipeline and a promising preclinical platform
- Stable finances: ~$75.5 million cash & investments as of 9/30/22; no debt
- Proprietary field-leading technology in underserved global indications backed by a strong IP portfolio
- Platform technology “validated” by strong existing partnerships with potential for many others
- Multiple potential value creating data and business development events projected in the next 12-24 months
- Seasoned management with domain expertise along with big pharma and emerging pharma experience

*SoC = standard-of-care

Proprietary platform technologies

CendR Platform™ - a targeted tissue penetration technology to enhance drug delivery to solid tumors

- Converts tumor stroma from barrier to conduit for efficient delivery of chemo-, targeted and immunotherapies
  - Delivery accomplished via co-administration or by tethering
- Selectively depletes intratumoral immunosuppressive cells
- Combination with many existing chemo- and immuno-therapeutics possible in a variety of indications

Tumor-Penetrating Nanocomplex (TPN) Platform™ - broad potential for delivery of nucleic acid-based therapies

- Addressing key challenges to delivery of nucleic acid-based drugs to treat solid tumor cancers
- Clinical development candidate identification targeted for 2023

CD34+ Cell Therapy Platform - designed to address diseases and conditions caused by ischemia

- CD34+ cells repeatedly demonstrated vascular repair in multiple organs and have been clinically studied in a variety of ischemic diseases by numerous investigators across many sites and countries
  - Consistent results of rigorous clinical studies comprising >1,000 patients published in peer reviewed journals[1-4]
    - Single treatments elicited durable therapeutic effects
    - Treatment generally well-tolerated

[1] Povsic, T. et al. *JACC Cardiovasc Interv*, 2016, 9 (15) 1576-1585
[2] Losordo, D.W. et al. *Circ Cardiovasc Interv*, 2012; 5:821–830
[3] Velagapudi P, et al, *Cardiovas Revasc Med*, 2018, 20(3):215-219
[4] Henry T.D., et al, *European Heart Jour* 2018, 2208–2216

Clinical development pipeline with broad therapeutic reach

LSTA1 (aka CEND-1), advancing in a variety of difficult-to-treat solid tumor applications

- Ongoing multiple studies in first-line, metastatic pancreatic ductal adenocarcinoma (mPDAC) in combination with standard-of-care (SoC) chemotherapy
- Basket trial initiation planned in 2023 expanding development to other solid tumors and additional anti-cancer drug combinations, including immunotherapies
- Granted Fast Track as well as Orphan Drug Designation by the U.S. FDA in PDAC

CD34+ autologous cell therapy development programs advancing to next development milestone

- No additional capital outlay necessary to reach identified milestones
- HONEDRA® (SAKIGAKE designated) advancing through Japanese regulatory process toward JNDA
- LSTA201 proof-of-concept (PoC) results expected in 1Q23
- XOWNA® development will continue if a partner is identified that can contribute the necessary capital

Noteworthy existing partnerships and the potential for many more

Strategic partnership in China with Qilu Pharmaceutical

- Exclusive rights to LSTA1 in China, Taiwan, Hong Kong and Macau
- Qilu assumes all development and commercialization responsibilities and costs in the licensed territories
- Potential for up to $225 million to Lisata for milestones and tiered double-digit royalties on potential sales

Clinical development collaboration with Roche in mPDAC

- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± atezolizumab as part of MORPHEUS trial

Additional partnership opportunities for broad applications of LSTA1 and the CendR Platform™

Ongoing discussions support goal to partner CD34+ programs

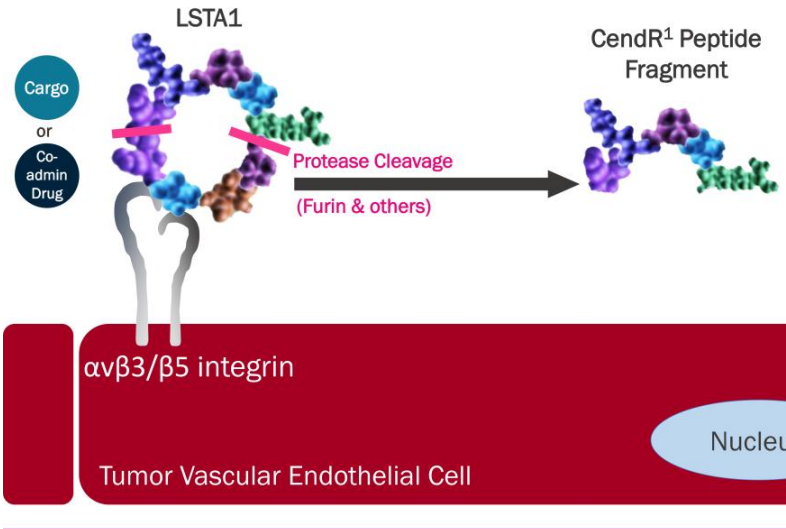
Robust development portfolio funded to next milestones

Sponsor/Funding Partner [Development Activity Venue]	Trial Products	Indication	Development Stage	Next Development Milestone
CendR Platform™ Programs				
Lisata/AGITG [Australia/New Zealand]	Gemcitabine/nab-paclitaxel with LSTA1 or placebo	First-Line Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)	Phase 2b (ASCEND)	Enrollment completion target 4Q23 First data expected 2024
Qilu [China]	Gemcitabine/nab-paclitaxel + LSTA1		Phase 1b/2	Preliminary data expected 2H23
Roche/Lisata [Multi-national]	Gemcitabine/nab-paclitaxel/LSTA1 ± atezolizumab		Phase 1b/2 (MORPHEUS)	Trial initiation target 1Q23
KUCC - IIT [United States]	LSTA1 + FOLFIRINOX + panitumumab*	Pancreatic, Colon and Appendiceal Cancers	Phase 1b/2 (CENDIFOX)	Enrollment completion target 4Q23 Data expected 2024
Lisata [United States]	SoC with LSTA1 or placebo	Various Solid Tumors	Phase 2a (Basket trial)	Trial initiation planned 1Q/2Q23
Lisata [United States]	TPN development candidate	Solid Tumor Cancer TBD	Preclinical	Development candidate ID target 2023 Phase 1 planned for 2024
CD34+ Platform Programs				
Lisata [United States]	HONEDRA® (LSTA12)	Critical Limb Ischemia and Buerger's Disease	Registration eligible	PMDA consultation underway
Lisata [Japan]	LSTA201	Diabetic Kidney Disease	Phase 1b – PoC	Data expected 1Q23
Lisata [United States]	XOWNA® (LSTA16)	Coronary Microvascular Dysfunction	Phase 2b (FREEDOM)	Partner sought to advance development

**Panitumumab may be added for colorectal or appendiceal patients without Ras mutation*


LSTA1
(aka CEND-1)
CendR Platform™

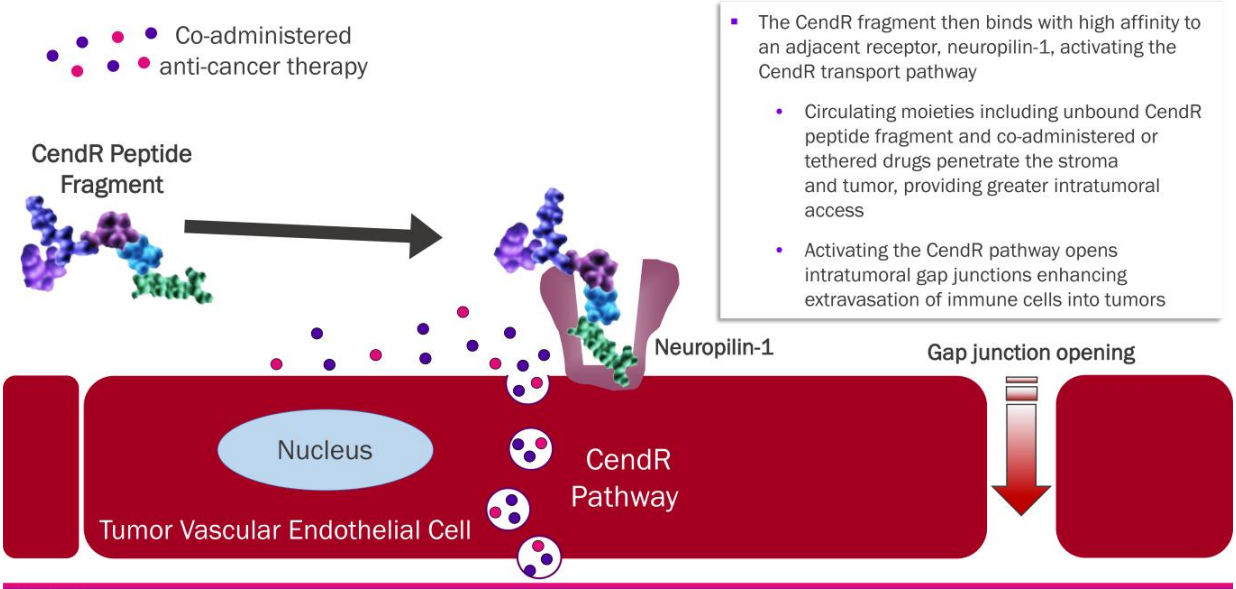
LSTA1 tumor targeting and microenvironment modifying MoA



- LSTA1 - 9 amino acid cyclic peptide; high binding specificity and affinity to αvβ3/β5 integrins that are selectively expressed on:
  - Tumor vascular endothelium
  - Cancer-associated fibroblasts, a major component of tumor stroma
  - Intratumoral immunosuppressive cells
- Once bound to αvβ3/β5 integrins, LSTA1 is cleaved by proteases (furin and others) that are up-regulated in tumors, releasing a C-end Rule (CendR) linear peptide fragment

[1] C-end Rule

LSTA1 tumor targeting and microenvironment modifying MoA (cont.)

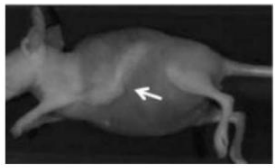


- The CendR fragment then binds with high affinity to an adjacent receptor, neuropilin-1, activating the CendR transport pathway
  - Circulating moieties including unbound CendR peptide fragment and co-administered or tethered drugs penetrate the stroma and tumor, providing greater intratumoral access
  - Activating the CendR pathway opens intratumoral gap junctions enhancing extravasation of immune cells into tumors

LSTA1 selectively and efficiently facilitates intratumoral delivery

Pancreatic ductal adenocarcinoma (arrow) imaging with Fluorescent Quantum Dots (FQDs) with and without LSTA1

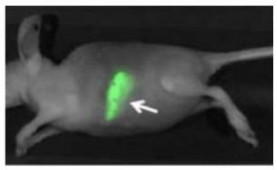
*+etch**



- FQD alone followed by etching solution to quench fluorescence in circulation

+LSTA1

*+etch**

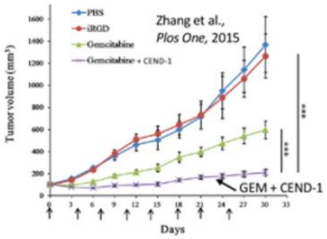


- FQD + LSTA1 followed by etching solution
  - LSTA1 enabled selective tumor penetration of FQDs

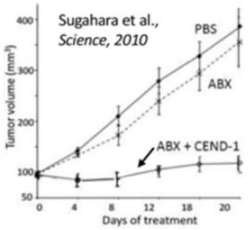
[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.

Increased tumor penetration enhances antitumor activity across range of treatment modalities

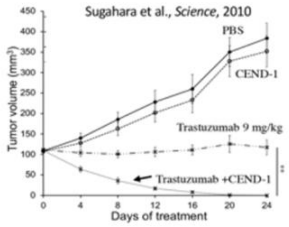
Lung cancer + gemcitabine



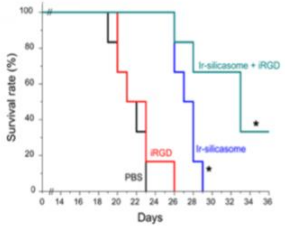
Breast cancer + nanoparticle Abraxane



Breast cancer + antibody (Herceptin®)

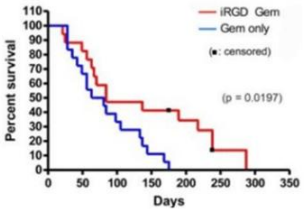


Pancreatic ductal adenocarcinoma



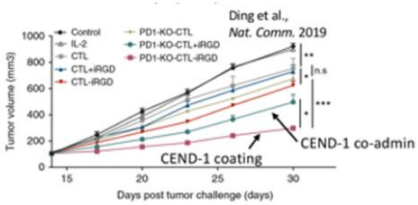
Orthotopically transplanted KPC PDAC tumors
CEND-1 + irinotecan nanoparticles (i.v. co-admin)

Pancreatic ductal adenocarcinoma



KPC mice genetically engineered to develop PDAC
CEND-1 + gemcitabine (i.v. co-admin)

GI cancer + adoptive cell therapy



[1] Hurtado de Mendoza et al, *Nature Comms*, 2021.
[2] Liu X et al., J Clin Invest, 2017.

Treatment of solid tumors represents a large unmet clinical need

Estimated New Cancer Cases and Deaths in the United States, 2022[1]

Estimated New Cases

Males			Females		
Prostate	268,490	27%	Breast	287,850	31%
Lung & bronchus	117,910	12%	Lung & bronchus	118,830	13%
Colon & rectum	80,690	8%	Colon & rectum	70,340	8%
Urinary bladder	61,700	6%	Uterine corpus	65,950	7%
Melanoma of the skin	57,180	6%	Melanoma of the skin	42,600	5%
Kidney & renal pelvis	50,290	5%	Non-Hodgkin lymphoma	36,350	4%
Non-Hodgkin lymphoma	44,120	4%	Thyroid	31,940	3%
Oral cavity & pharynx	38,700	4%	Pancreas	29,710	3%
Leukemia	35,810	4%	Kidney & renal pelvis	28,710	3%
Pancreas	32,970	3%	Leukemia	24,840	3%
All Sites	**983,160**	**100%**	**All Sites**	**934,870**	**100%**

Estimated Deaths

Males			Females		
Lung & bronchus	68,820	21%	Lung & bronchus	61,360	21%
Prostate	34,500	11%	Breast	43,250	15%
Colon & rectum	28,400	9%	Colon & rectum	24,180	8%
Pancreas	25,970	8%	Pancreas	23,860	8%
Liver & intrahepatic bile duct	20,420	6%	Ovary	12,810	4%
Leukemia	14,020	4%	Uterine corpus	12,550	4%
Esophagus	13,250	4%	Liver & intrahepatic bile duct	10,100	4%
Urinary bladder	12,120	4%	Leukemia	9,980	3%
Non-Hodgkin lymphoma	11,700	4%	Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,710	3%	Brain & other nervous system	7,570	3%
All Sites	**322,090**	**100%**	**All Sites**	**287,270**	**100%**

[1] CA A Cancer J Clinicians, Volume: 72, Issue: 1, Pages: 7-33, First published: 12 January 2022, DOI: (10.3322/caac.21708)

Pancreatic cancer is among the deadliest cancers in the U.S. with a five-year survival rate of only 11%

An estimated 609,360 people will die from cancer in 2022, corresponding to ~1,670 deaths per day

In the U.S. alone, solid tumors account for over 90% of new cancer cases

It is estimated that more than 1.9 million new cases of cancer will be diagnosed in 2022

LSTA1 Phase 1b results reinforce promise of improving SoC efficacy

First-line, mPDAC patients from 3 sites in Australia;

- n=31 (29 evaluable); LSTA1 in combination with SoC (gemcitabine + nab-paclitaxel)
- LSTA1 well-tolerated, no dose-limiting toxicities; safety with LSTA1 consistent with SoC alone
- Unprecedented improvement of SoC anti-tumor activity [1,2]
  - Overall Response Rate (PR+CR=ORR) 59% (vs. 23%) including Complete Response
  - Disease Control Rate at 16 weeks 79.3% (vs. 48%)
  - CA19-9 circulating tumor biomarker reductions in 96% of patients (vs. 61%)
  - Median Progression-Free Survival 9.7 months (vs. 5.5 months[2])
  - Median Overall Survival 13.2 months (vs. 8.5 months[2])

[1] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.
[2] Von Hoff D, et al., *New England Journal of Medicine*, 2013.

Ongoing and Planned LSTA1 Clinical Trials

ASCEND: Phase 2b randomized, double-blind trial in AUS and NZ

Sponsor/Partner	▪ Lisata/Australasian Gastro-Intestinal Trials Group (AGITG) in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney ▪ AGITG/LSTA co-funded
Design	▪ Phase 2b randomized, double-blind study in mPDAC
Study Size	▪ ~125 subjects (~40 sites planned in Australia, New Zealand and, possibly, Ireland)
Endpoints	▪ Primary: Progression Free Survival ▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate
Control/Comparator	▪ SoC chemotherapy (gemcitabine + nab-paclitaxel) with LSTA1 or placebo
Objective	▪ Corroborate Phase 1b results in a placebo-controlled study ▪ Possibly determine if a second dose of LSTA1 further improves patient outcomes
Timing	▪ Enrollment completion target late 2023/early 2024 ▪ Earliest possible data 2024

LSTA1 Phase 1b/2 trial in China

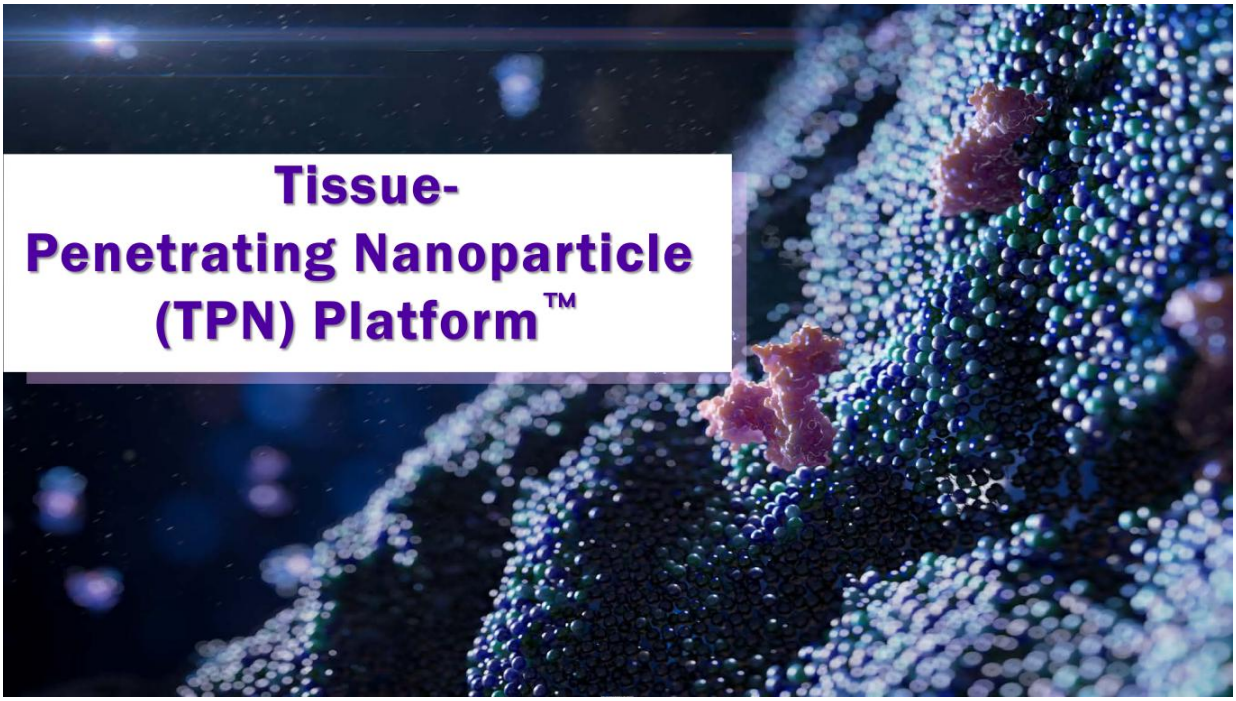
Sponsor/Partner	▪ QILU Pharmaceutical (funds all development in China)
Design	▪ Phase 1b/2 open-label study in advanced mPDAC patients of Chinese ethnicity
Study Size	▪ 50 subjects (~15 sites)
Endpoints	▪ Primary: AEs, SAEs, Objective Response Rate, Duration Response Rate, Disease Control Rate, Overall Survival, and Progression Free Survival ▪ Secondary: Pharmacokinetic parameters
Control/Comparator	▪ SoC chemotherapy (gemcitabine + Qilu-produced nab-paclitaxel) in combination with LSTA1
Objective	▪ Evaluate safety, pharmacokinetics and preliminary efficacy of LSTA1 added to SoC in Chinese patients with mPDAC
Timing	▪ Preliminary data expected 2H23

CENDIFOX: Phase 1b/2 trial in U.S.

Sponsor/Partner	▪ University of Kansas Medical Center (Investigator initiated trial) ▪ KUCC funded; Lisata provides LSTA1
Design	▪ Phase 1b/2 open-label study in pancreatic, colon and appendiceal cancers
Study Size	▪ 50 subjects
Endpoints	▪ Primary: Drug Safety ▪ Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate
Control/Comparator	▪ SoC chemotherapy (neoadjuvant FOLFIRINOX-based therapies with LSTA1)
Objective	▪ Evaluate the safety of LSTA1 in combination with neoadjuvant FOLFIRINOX-based therapies for the treatment of pancreatic, colon, and appendiceal cancers
Timing	▪ Enrollment completion target 4Q23 ▪ Data readouts possible throughout 2023 with complete results expected 2024

Planned LSTA1 Phase 2 proof-of-concept basket trial

Sponsor/Partner	▪ Lisata
Design	▪ Phase 2, randomized, double-blind, placebo-controlled, proof-of-concept trial in multiple advanced solid tumor types (U.S.) with corresponding standards of care
Study Size	▪ 160 (assuming 4 tumor types)
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Control/Comparator	▪ Tumor-type specific SoC chemotherapy in combination with LSTA1 or placebo
Objective	▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors
Timing	▪ Trial initiation target: 1Q/2Q23


Tissue-
Penetrating Nanoparticle
(TPN) Platform™

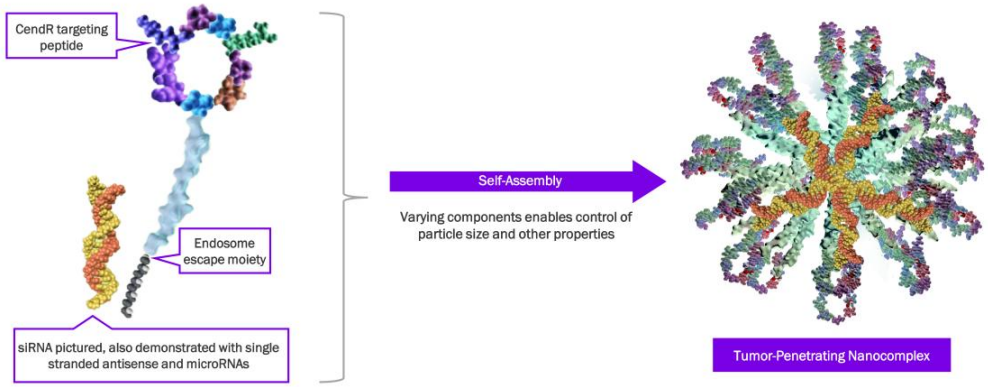
TPN Platform™ for nucleic acid medicine delivery to solid tumors

DELIVERY ISSUES LIMIT ANTICANCER APPLICATIONS OF RNA-BASED THERAPEUTICS

- Early antisense oligonucleotide (ASO) and small interfering RNA (siRNA) anticancer programs failed to translate preclinical efficacy to clinical success
  - Tumor stroma serves as primary impediment to effective delivery
  - High doses to drive intratumoral concentration resulted in on- and off-target side effects, including, but not limited to, clotting factors and renal toxicities
  - >95% of ASO and siRNA drugs sequestered in endosomes
- Passive targeting (i.e., lipid nanoparticles) appears ineffective
- Non-targeted cell-/tissue-penetrating moieties can disrupt unintended tissues
- Moieties to target tumor increase bulk and may exacerbate problem of transiting stroma

Targeted approach to transit tumor stroma may enable effective solid tumor treatment

TPN Platform™ addresses nucleic acid tumor delivery challenges



- Peptides provide tumor and/or immune cell targeting
- Unique CendR pathway activation to penetrate stroma and deliver efficacious drug concentrations to all layers of solid tumors
- Technologies to evade endosome sequestration
- Targeted tissue penetration drives dose- and toxicity-sparing potency
- Ease of synthesis vs. biologics such as virus-like particles, Ab-conjugates or exosomes


CD34+ Cell Therapy
Platform Technology


XOWNA®
[LSTA16 (formerly known as CLBS16)]
Coronary Microvascular Dysfunction
(USA)

XOWNA® development status

Summary

- Coronary Microvascular Dysfunction (CMD) represents a large unmet medical need
  - Deficient heart microvasculature ***without large vessel obstructive disease*** causing frequent, severe angina
  - Not treatable by stents/bypass; responds poorly or not at all to available pharmacotherapies
  - U.S. CMD population potentially treatable by XOWNA® ranges from ~415,000 to ~1.6 million patients[1]
  - Compelling Phase 2a (published ESCaPE-CMD trial) results show the potential of XOWNA® to significantly improve symptoms of CMD
  - Phase 2b (FREEDOM) trial impacted directly and indirectly by COVID pandemic resulted in insurmountable enrollment rate challenges and population heterogenicity; trial enrollment suspended in May 2022 after ~1/3 of the intended subjects enrolled

Next Steps

- Analysis of results of FREEDOM Trial subjects completing 6-month follow-up along with KOL input suggests that execution of a redesigned FREEDOM-like trial is an appropriate next step
  - Cost of such trial is financially challenging in a "go-it-alone" strategy
- XOWNA® development will continue if a partner is identified that contributes the necessary capital

[1] Marinescu MA, et al. JACC Cardiovasc Imaging. 2015;8:210-220


HONEDRA®
[LSTA12 (formerly known as CLBS12)]
Critical Limb Ischemia
(Japan)
SAKIGAKE designated – Japan
Orphan Drug designated (Buerger's disease) - USA
Advanced Therapeutic Medicinal Product (ATMP) designated – EU

Indication: critical limb ischemia (CLI)

- Severe arterial obstruction impeding blood flow in the lower extremities
  - Includes severe rest pain and non-healing ulcers
- Buerger's disease (BD: inflammation in small and medium arteries) is a form of CLI associated with a history of heavy smoking (orphan population)
- Patients with no-option CLI have persistent symptoms even after bypass surgery, angioplasty, stenting and available pharmacotherapy
- CLI has been categorized as Rutherford Classification Stages[1]
  - Stages: 1-3 (mild to severe claudication); 4 (rest pain); 5 (minor tissue loss); 6 (major tissue loss)
  - CLI patients are at high risk of amputation and death with increasing Rutherford score
- Multi-million-dollar opportunity with an increasing prevalence of arteriosclerosis obliterans (ASO) and CLI in Japan
- Positive previously published Phase 2 results in Japan[3,4]

[1] Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8
[3] Kinoshita et al, Atherosclerosis 224 (2012) 440-445
[4] Losordo, D.W. et al, Circulation 2012; 5(6):821-830

HONEDRA® registration-eligible study in Japan

Primary Endpoint	▪ Time to continuous CLI-free (2 consecutive monthly visits, adjudicated independently)
Target Study Size	▪ 35 subjects; recruited across 12 centers in Japan • 30 with no-option CLI (ASO) + 5 with BD; all Rutherford category 4 or 5
Dose	▪ Up to 10^6 cells/kg of HONEDRA® (LSTA12)
Control/Comparator	▪ SoC: wound care plus drugs approved in Japan • Including antimicrobials, antiplatelets, anticoagulants and vasodilators
Mode of Administration	▪ Intramuscular, 20 injections in affected lower limb in a single treatment
Objective	▪ Demonstrate a trend toward efficacy and acceptable safety to qualify for consideration of early conditional approval under Japan's Regenerative Medicine Development Guidelines

HONEDRA® development next steps

- Combined CLI and BD interim data suggest trend toward efficacy and acceptable safety
  - HONEDRA® was safe and well tolerated
  - Treatment group reached CLI-free status faster than SoC group (primary endpoint)
- Consultation process with the Pharmaceuticals & Medical Devices Agency (PDMA) is underway in support of the planned filing of a Japan New Drug Application


LSTA201
(formerly known as CLBS201)
Diabetic Kidney Disease

LSTA201 in diabetic kidney disease (DKD)

Development Rationale

- The stages of CKD are determined by GFR rate, an indication of how well the kidneys are filtering blood[1]
- CKD is often associated with progressive microvasculature damage and loss[2,3]
- Preclinical studies show that microcirculation replenishment improves kidney function
- CD34+ cells are promoters of new capillary growth, improving the microvasculature
- Therapies currently available and/or expected to be available over the next 5–10 years will slow the progression of CKD/DKD
- A regenerative DKD therapy (i.e., one that reverses disease course) could represent a medical and pharmacoeconomic breakthrough

Clinical Strategy

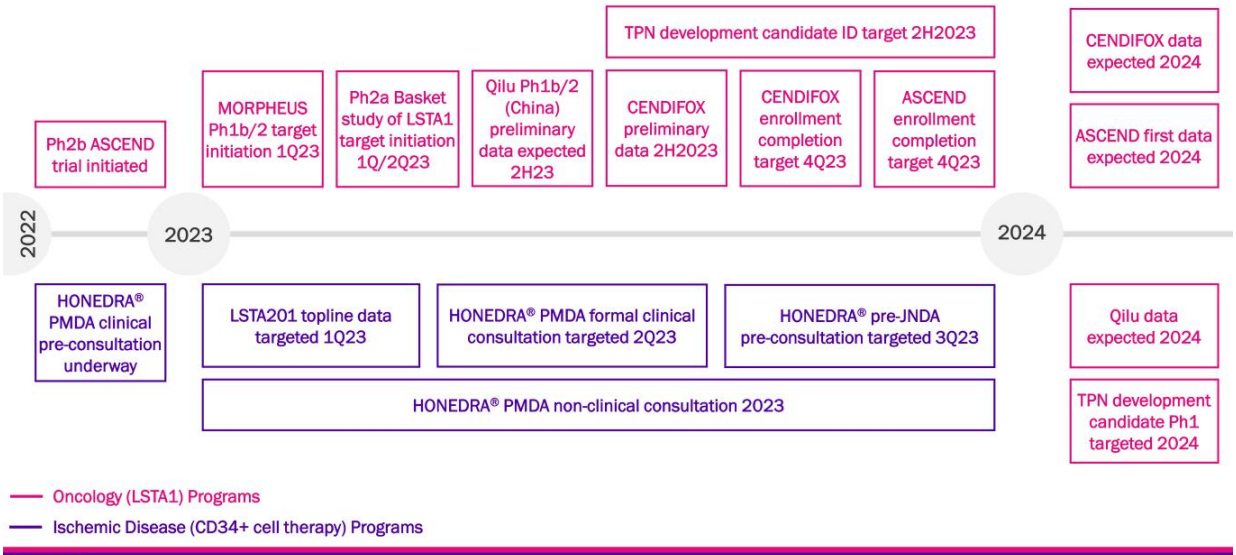
- To demonstrate that CD34+ cell mobilization, donation, and administration can be tolerated by patients with CKD and type 2 diabetes
- To demonstrate that regeneration of the kidney microcirculation using CD34+ cell therapy improves kidney function

[1] 2020 Dallas Nephrology Associates.
[2] Chade AR. (2017) Small Vessels, Big Role: Renal Microcirculation and Progression of Renal Injury. Hypertension; 69(4):551-563.
[3] *Zuk, Anna & Bonventre, Joseph. (2016). Annual Review of Medicine. 67. 293-307. 10.1146/annurev-med-050214-013407.*

LSTA201: Phase 1b open-label, proof-of-concept study in U.S.

Endpoints	▪ Change in eGFR compared to baseline, assessed at 6 months ▪ Change in Urine albumin-to-creatinine ratio (UACR) and urine protein-to-creatinine ratio (UPCR) from baseline to 3 and 6 months
Study Size	▪ 6 patients (1 sentinel - unilateral inj., 1 sentinel - bilateral inj., 4 bilateral inj. patients)
Dose	▪ 1×10^6 – 300×10^6 cells administered as a one-time infusion
Patient Population	▪ Stage 3b DKD
Design	▪ Open-label, proof-of-concept Phase 1b study
Mode of Administration	▪ Intra-arterial injection into one or both renal arteries
Timing	▪ Top-line data target for all subjects: 1Q23

Anticipated milestones



Key financial information

Cash & Investments: As of September 30, 2022	$75.5 million
Nine months ended September 30, 2022, Operating Cash Burn[1]:	$17.0 million
Debt as of September 30, 2022:	$0
Common Shares Outstanding: As of September 30, 2022	7.9 million shares
Options Outstanding as of September 30, 2022: Exercise Price: $0.02 - $4.22 = 1,127,000 shares Exercise Price: > $4.22 = 272,000 shares	1.4 million shares[2]
Warrants Outstanding as of September 30, 2022: Weighted Average Exercise Price: $42.57	1.4 million shares

[1] Excludes $2.3 million in net proceeds from sale of New Jersey NOLs
[2] Includes 1.2 million options assumed through the merger at a weighted average exercise price of $3.77

Investment highlights

| NOVEL TECHNOLOGY TO IMPROVE EFFICACY OF ANTI-CANCER DRUGS FOR SOLID TUMORS |

| EXISTING CAPITAL EXPECTED TO FUND ANTICIPATED MILESTONES | EXISTING STRATEGIC PARTNERSHIPS |

- Nasdaq-listed with a focused mid-late-stage clinical development pipeline and a promising preclinical platform
- Stable finances: ~$75.5 million cash & investments as of 9/30/22; no debt
- Proprietary field-leading technology in underserved global indications backed by a strong IP portfolio
- Platform technology “validated” by strong existing partnerships with potential for many others
- Multiple potential value creating data and business development events projected in the next 12-24 months
- Seasoned management with domain expertise along with big pharma and emerging pharma experience

**SoC = standard-of-care*

LISATA THERAPEUTICS

Targeted Therapy **Delivered**

Investor Relations Contact:
John D. Menditto
VP, IR & Corporate Communications
o: (908) 842-0084 | e: jmenditto@caladrius.com

Nasdaq: LSTA | www.lisata.com